

Attached to Protocol: 18-210
Principal Investigator: Kimberly Noble
IRB Protocol Title: Baby's First Years

Consent Number: 18-210
Participation Duration: Three Years
Anticipated Number of Subjects: 250

Contact	Title	Contact Type	Numbers
Kimberly Noble	MD, PhD	Principal Investigator	(212) 678-3486
Lauren Meyer	Project Director	Administrative	(608) 291-7359

This study is sponsored by National Institute of Child Health and Human Development and national and local private foundations.

Invitation to Participate

The goal of this research study is to gain an understanding of the family experiences and backgrounds of families with new babies. We hope that examining these factors during the first three year of child's life will help us understand how they influence how children learn and grow, and how programs can support families during the first years of their child's life.

This kind of information will be collected in the form of interviews, home visits, and a university visit. You are being asked to participate in this study because your baby was born in this hospital and you meet other criteria including age and other demographic characteristics. Taking part in this research study is voluntary. If you decide to participate, we may approach you about participation in future research, including a phone interview or home visit when your child is 1 year old, a home visit when your child is 2 years old, and a university visit when your child is 3 years old. You may also be contacted for a special smaller study to talk more about your day-to-day experience raising your baby.

The interviews will be conducted by University of Michigan interviewers on behalf of researchers from University of California Irvine, Columbia University's Teachers College, New York University, and University of Wisconsin.

Important Information about the Research Study

This form will provide information about the study so that you may decide whether or not to participate. This form includes information about:

- ✓ Why the study is being done
- ✓ The things you will be asked to do in the study
- ✓ Any known risks
- ✓ Any potential benefits
- ✓ Available options, other than taking part in this study

I will discuss the study with you and answer any questions that you may have. Take as much time as you need to decide whether you want to take part in this study.

The things you will be asked to do in the study

Today we will ask you to participate in a Baseline interview. A member of the research staff will ask you questions about you, your baby, and your family. We will ask about your work and educational background. We will ask about your family's background, your household income, assets and debts. We will ask for your relationship with the baby's father and each household member's involvement in caring for your baby. We will conclude by asking about your current neighborhood.

After completing the Baseline interview, we may contact you again for participation in future research opportunities described below. Before each follow-up interview, you will be able to choose whether or not you would like to participate in that part of the research study.

One Year Assessment

If you choose to continue, at 12 months you may be selected for a phone interview or home visit. At that time, we will collect information about your child's health and general developmental milestones, your health, as well as information about your income and family life. The entire interview will take 90 minutes to complete. You may choose to skip any questions you do not wish to answer.

Two Year Assessment

If you chose to continue, we will invite you to complete a home visit when your baby is 2 years old. During this visit you and your child will be invited to participate in the following activities:

- We will ask you questions related to your child's development, your experiences with your child, and we will assess your child's development. You and your child will participate in an observed play activity so we can see how you interact with each other.
- You and your child will be asked to provide a hair sample by cutting (not pulling) a small section of hair on the crown of the head, so that we can measure hormone levels.
- You and your child will be asked to provide a saliva sample, so that we can measure hormone levels.

The entire visit will take 90 minutes. You may choose to skip any activities you do not wish to participate in.

Three Year Assessment

If you chose to continue, we will invite you to participate in a developmental assessment when your baby is 3 years old. To participate, we will provide transportation to come to our university lab. During this visit you and your child will be invited to participate in the following activities:

- We will ask you questions related to your child's development, your experiences with your child, and we will assess your child's development.
- Your child will participate in a variety of tests to measure your child's cognitive and academic skills.
- We will measure your child's height and weight and your height and weight.
- We will invite your child to have an EEG, this requires wearing a cap with harmless electrodes on his or her head to measure brain activity.

The entire visit will take 2 hours. You may choose to skip any activities you do not wish to participate in.

Risks and Burden

Both your and your child's participation in this study is voluntary. Declining to participate will involve no penalty or loss benefits to which you or your child are otherwise entitled. Also, you or your child may choose to discontinue participation at any time.

The risks for participating may involve boredom or frustration. If at any time your child wishes to take a break (for example, a break for feeding or rest) or stop an activity, they are free to do so. You may find some of the questions embarrassing or too sensitive. You may choose to not answer a question or to stop participating at any time.

We will minimize any inconvenience. Although it is not a risk, taking part in this study involves the inconvenience of giving up your time in order to complete interviews and assessments.

If the research team suspects child abuse or neglect, we will report this to the appropriate authorities.

Benefits

There are no direct benefits from participating in this research study. This study may be helpful in understanding the factors that affect how children learn and grow.

Confidentiality

Researchers will keep all of your personal data private and secure. Your information will not be seen by anyone outside of the research team and will be kept confidential as promised. Unanticipated problems, such as a stolen password, may occur, although such incidences are highly unlikely. Our research team will take the utmost care to protect your and your child's privacy.

The researchers plan to publish the results of this study. To protect your privacy, they will not include any information that could directly identify you. They will protect the confidentiality of your research records by

assigning a unique participant number and never associating your name and any identifying information with responses collected during the interview. After completing the interview, University of Michigan will transfer your data to a secure storage at the University of Wisconsin where the data will be processed for use by the research team. The files linking your name to the participant number will be kept in a password-protected database to which only key research staff will have access. When researchers report the study findings they will only report information in general aggregated terms so participants cannot be identified.

It is possible that other people may need to see the information we collect about you. These people work for the universities responsible for this research and government offices that are responsible for making sure the research is done safely and properly.

The following individuals and/or agencies will have access to your interview information:

- Interviewers from University of Michigan will conduct the interviews and transfer the data for secure storage at University of Wisconsin.
- Researchers from University of California – Irvine, Columbia University's Teachers College, New York University, and University of Wisconsin will use the data for research analysis purposes. Your identity as a research subject will be protected and your name will not be associated with the interview data.
- Authorities from Teachers College, including the Institutional Review Board, and from the Office for Human Research Protection may also access your data.

Officials from this hospital (the hospital in which you gave birth) will have access to your signed consent form upon request, but will not have access to your interview information.

This study holds a Certificate of Confidentiality (CoC) that offers additional protections for your identifiable research information, and records. The most important protection is that members of the research team cannot be forced to disclose or provide any of your private identifiable information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding unless you provide permission. Disclosure of your research information may only occur in limited instances.

If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

You and your family must also actively protect your own privacy. If you give consent to anyone else (an insurer or employer, for example) to receive research information, then researchers cannot use the certificate to withhold this information. Researchers must release information as required by Federal, State or local laws, or to prevent serious harm to you or someone else.

Compensation

Your family will receive a payment of \$50 in cash for participating in the interview today. If you choose to participate in future visits, you will receive \$50 each for the year one and year two home visit for a total of

\$100. You will also receive \$200 and coverage of transportation costs for the year 3 university visit. If you choose to withdraw from an interview before it is complete, you will still be paid for your participation for that specific visit or assessment. However, you will not be compensated for future assessments that you do not initiate.

Additional Costs

There are no costs to you for taking part in this study.

Voluntary Participation

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed, your data will be retained.

Additional Information

What will happen to the information we collect about you after the study is over?

Without sharing your identity, we may share your de-identified research data with other investigators without asking for your consent again.

A description of this study will be posted on a public website, <http://ClinicalTrials.gov>, and summary results of this study will be posted on this website at the conclusion of the research, as required by the National Institutes of Health (NIH), the study sponsor. No information that can identify you will be posted."

Who to Contact

If you have any questions or concerns about the study, you may contact principal investigator: Kimberly Noble, kgn2106@tc.columbia.edu, (212) 678-3486 or the project director: Lauren Meyer, bfystudy@gmail.com, (608) 291-7359.

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research. If you have any questions about your rights as a research participant, you should contact the Teachers College Institutional Review Board at:

525 W 120th St
New York, NY 10027
Telephone: (212) 678-3000
Email: irb@tc.edu

More information about taking part in a research study can be found on the IRB website
<http://www.tc.columbia.edu/institutional-review-board/>

If you have any concerns with the University of Michigan interviewers, please contact the following: University of Michigan, Health Sciences and Behavioral Sciences Institutional Review Board
2800 Plymouth Road
Building 520, Room 1169 Ann Arbor, MI 48109-2800
Phone: (734) 936-0933 or toll free, (866) 936-0933 Email: irbhsbs@umich.edu

Statement of Consent

I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits, and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Future Research Opportunities

We also may contact you with opportunities to participate in additional data collection in the future. Please Initial if you agree to have us contact you for future opportunities:

Signature

Parent/Guardian

Print Name _____ Signature _____ Date _____

Person Obtaining Consent

Print Name _____ Signature _____ Date _____